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2001 EDITION

PROCEDURES AND GENERAL REQUIREMENTS

NVLAP®

National Voluntary Laboratory Accreditation Program

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[2] Some elements at Boulder, CO.

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National Voluntary Laboratory Accreditation Program

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V. R. White, D. F. Alderman, and C. D. Faison, Editors

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Office of Standards Services
Technology Services

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Donald L. Evans, Secretary

Technology Administration
Karen H. Brown, Acting Under Secretary of Commerce for Technology

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Foreword

The 2001 edition of NIST Handbook 150 incorporates revisions to the procedures and general requirements of the National Voluntary Laboratory Accreditation Program (NVLAP), set forth in Part 285 of Title 15 of the U.S. Code of Federal Regulations. These revisions were published in the *Federal Register* on May 30, 2001, and became effective on June 29, 2001. The NVLAP procedures were revised to ensure continued consistency with international standards and guidelines, specifically those currently found in ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*, and ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems–General requirements for operation and recognition*.

The requirements in Sections 4 and 5 of this edition (formerly Subpart D) are identical to those found in clauses 4 and 5 of ISO/IEC 17025:1999. They must be met in order for a laboratory to be recognized as competent to carry out tests and/or calibrations. Major changes from the previous edition of the handbook include the following:

- In Section 4, *Management requirements*, there are additional or changed requirements in the areas of document control; requests, tenders, and contracts; purchasing; nonconforming work; corrective action; preventive action; and records. These additions and changes incorporate and/or are consistent with ISO 9001:1994 requirements. A new clause, *Service to the client*, prescribes cooperation with clients and provides guidance on such cooperation.

- In Section 5, *Technical requirements*, the requirements are described in greater detail, but most concepts are not "new" for accredited laboratories. There is continued reference to client needs and greater emphasis and/or more detailed requirements on method validation; estimation of measurement uncertainty/traceability for **testing** laboratories; and provision for inclusion of interpretations and opinions on test reports. A sampling plan will be required where methods or specifications do not specify sampling procedures.

In addition to these changes, the 2001 edition has been completely restructured to conform with internationally accepted rules for the structure and drafting of standards and similar technical documents, and to promote ease of use and understanding. The major part of Sections 1 through 3 (formerly Subparts A through C) remains unchanged, although the restructuring tends to suggest otherwise.

The 2001 edition supersedes and replaces the 1994 edition of NIST Handbook 150.

Annexes A and B form a normative part of this handbook, meaning that they are integral parts of the handbook and contain provisions to which it is necessary to conform in order to claim compliance with the handbook requirements. The annexes were added to provide information and guidance for the implementation of NVLAP's policies on referencing NVLAP accreditation and traceability of calibrations.

Introduction

The National Voluntary Laboratory Accreditation Program (NVLAP) accredits testing and calibration laboratories that are found competent to perform specific tests or calibrations, or types of tests or calibrations. NIST Handbook 150 sets forth the basic procedures under which NVLAP operates, and the general accreditation requirements for testing and calibration laboratories. Sections 4 and 5 and the annexes of the handbook contain the general requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

NVLAP operates an accreditation system that is compliant with ISO/IEC Guide 58, which requires that the competence of applicant laboratories be assessed by the accreditation body against all of the requirements of ISO/IEC Guide 25; however, in 1999, ISO/IEC Guide 25 was cancelled and replaced by ISO/IEC 17025. NVLAP uses ISO/IEC 17025 as the basis for the accreditation of testing and calibration laboratories. The managerial and technical requirements of ISO/IEC 17025 are contained in their entirety in Sections 4 and 5 of this handbook.

The growth in the use of quality systems has increased the need to ensure that laboratories that form part of larger organizations or offer other services can operate to a quality system that is seen as compliant with the 1994 editions of ISO 9001 or ISO 9002, as well as with ISO/IEC 17025. Care was taken during the drafting of ISO/IEC 17025 to incorporate all those requirements of ISO 9001 and ISO 9002 that are relevant to the scope of testing and calibration services that are covered by a laboratory's quality system. Testing and calibration laboratories that comply with the requirements of this handbook will also operate in accordance with ISO 9001 or ISO 9002. However, ISO 9001 or ISO 9002 registration does not by itself demonstrate the competence of the laboratory to produce technically valid data and results.

The acceptance of testing and calibration results among economies should be facilitated if laboratories comply with this handbook and obtain NVLAP accreditation. NVLAP has entered into mutual recognition arrangements with equivalent accreditation bodies that comply with ISO/IEC Guide 58 and applicable regional documents. The use of this handbook will promote cooperation between laboratories and other bodies, and assist in the exchange of information and experience and in the harmonization of standards and procedures.

1 General information

1.1 Purpose and scope

1.1.1 NIST Handbook 150 sets forth the procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration laboratories. Supplementary technical and administrative requirements are provided in supporting handbooks (NIST Handbook 150 series) and documents, as needed, depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

1.1.2 This handbook is to be used by laboratories in developing their quality, administrative, and technical systems that govern their operations. Laboratory clients, regulatory authorities, and accreditation bodies may also use it in confirming or recognizing the competence of laboratories.

1.1.3 Notes are given to provide clarification of the text, examples, and guidance. They do not contain requirements and do not form an integral part of the accreditation criteria.

In Section 5 of the handbook, the term ***NVLAP Note*** indicates NVLAP reference to or clarification of a particular requirement.

1.1.4 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this handbook.

1.1.5 If testing and calibration laboratories comply with the requirements of this handbook, they will operate a quality system for their testing and calibration activities that also meets the requirements of ISO 9001:1994 when they engage in the design/development of new methods, and/or develop test programs combining standard and nonstandard test and calibration methods, and ISO 9002:1994 when they only use standard methods.

1.2 Organization of handbook

Section 1 describes considerations which relate in general to all aspects of NVLAP. Section 2 describes how LAPs are requested, developed, announced, and terminated. Section 3 describes the process for accrediting laboratories. Sections 4 and 5 provide the criteria for NVLAP accreditation found in clauses 4 and 5 of ISO/IEC 17025:1999. Annexes A and B present requirements for referencing NVLAP accreditation and achieving traceability, respectively.

1.3 Description of NVLAP

1.3.1 NVLAP is a U.S. Government entity administered by the National Institute of Standards and Technology (NIST), an agency of the Department of Commerce. NVLAP accredits testing and calibration laboratories found competent to perform specific tests or calibrations.

1.3.2 NVLAP operates a quality system that is compliant with ISO/IEC Guide 58:1993.

1.3.3 NVLAP is a voluntary system which:

a) provides a mechanism for the recognition of testing and calibration laboratories based on internationally accepted standards and procedures;

b) provides laboratory management with documentation for use in the development and implementation of their quality systems;

c) identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

d) provides laboratories with a process to aid them in reaching a higher level of performance, resulting in the generation of improved engineering and product information; and

e) promotes the acceptance of test and calibration results between economies and accreditors to support trade facilitation activities.

1.3.4 NVLAP is comprised of a series of LAPs established on the basis of requests and demonstrated need. The Chief of NVLAP does not unilaterally propose or decide the scope of a LAP. The specific tests and calibrations, types of tests and calibrations, or standards to be included in a LAP are determined by an open process during the establishment of the LAP (Section 2).

1.3.5 NVLAP programs are established:

a) for public and private testing and calibration laboratories, including commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state, and local government laboratories;

b) to meet legal requirements, regulations or codes, and contract specifications, or to recognize laboratories found competent to meet the needs of their clients; and

c) as the basis for guidance to facilitate agreements on mutual recognition of accreditation of laboratories between NVLAP and other accreditation systems.

1.3.6 NVLAP accreditation is:

a) based on evaluation of a laboratory's management and technical qualifications and competence for conducting specific test methods, measurements, and services in specified fields of testing or calibration;

b) granted only after thorough evaluation of an applicant has demonstrated that all NVLAP criteria have been met;

c) acknowledged by the issuance of two documents to attest to that compliance: (1) a Certificate of Accreditation, and (2) a Scope of Accreditation, which details the specific test methods, measurements and services for which a laboratory has been accredited; and

d) administered in a nondiscriminatory manner, and not conditional on the size of a laboratory or on its membership in any association or group.

Accreditation does not relieve a laboratory from complying with applicable federal, state, and local laws and regulations.

1.4 References

The following documents are referenced in the text or notes of this handbook.

— ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*.

— BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML:1993, *International Vocabulary of Basic and General Terms in Metrology* (VIM).

— BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML:1993, *Guide to the Expression of Uncertainty in Measurement* (GUM).

— ISO 8402:1994, *Quality management and quality assurance – Vocabulary*.

— ISO 9001:1994, *Quality systems - Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*.

— ISO 9002:1994, *Quality systems - Model for Quality Assurance in Production, Installation, and Servicing*.

— ISO Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons* – Part 1*: Development and operation of proficiency testing schemes*.

— ISO Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons* – Part 2*: Selection and use of proficiency testing schemes by laboratory accreditation bodies*.

— ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*.

— ISO/IEC Guide 2:1996, *Standardization and related activities – General vocabulary*.

— ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems – General requirements for operation and recognition*.

— NIST Technical Note 1297: *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 Edition.

1.5 Definitions

For the purposes of this handbook, the following definitions apply.

1.5.1 Accreditation: Formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of tests or calibrations.

1.5.2 Accreditation criteria: Set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

1.5.3 Accuracy of measurement: Closeness of the agreement between the result of a measurement and a true value of the measurand. (See also **uncertainty of measurement**.)

NOTE 1 "Accuracy" is a qualitative concept.

NOTE 2 The term *precision* should not be used for "accuracy."

[VIM:1993, 3.5]

1.5.4 Approved Signatory: Individual who is recognized by NVLAP as competent to sign accredited laboratory test or calibration reports.

NOTE The Approved Signatory is responsible for the technical content of the report and is the person to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report. Approved Signatories shall be persons with responsibility, authority and technical capability within the organization for the results produced.

1.5.5 Assessment, on-site: On-site examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

1.5.6 Authorized Representative: Individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements.

1.5.7 Best measurement capability: Smallest uncertainty of measurement a laboratory can achieve within its scope of accreditation, when performing more-or-less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve or reproduce a unit of that quantity or one or more of its values, or when performing more-or-less routine calibrations of nearly ideal measuring instruments designed for the measurement of that quantity.

1.5.8 Calibration: Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

NOTE 1 The result of a calibration permits either the assignment of values of measurands to the indications or the determination of corrections with respect to indications.

NOTE 2 A calibration may also determine other metrological properties such as the effect of influence quantities.

NOTE 3 The result of a calibration may be recorded in a document, sometimes called a *calibration certificate* or a *calibration report*.

[VIM:1993, 6.11]

NOTE 4 The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve.

1.5.9 Calibration method: (See **method of measurement**.)

1.5.10 Calibration procedure: (See **measurement procedure**.)

1.5.11 Certificate of Accreditation: Document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. A current Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied by a Scope of Accreditation.

1.5.12 Certified reference material (CRM): Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence. (See also **reference material**.)

NOTE 1 The definition of a "reference material certificate" is given in VIM:1993, 4.2.

NOTE 2 CRMs are generally prepared in batches for which the property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.

NOTE 3 The certified properties of certified reference materials are sometimes conveniently and reliably realized when the material is incorporated into a specially fabricated device, e.g., a substance of known triple-point into a triple-point cell, a glass of known optical density into a transmission filter, spheres of uniform particle size mounted on a microscope slide. Such devices may also be considered as CRMs.

NOTE 4 All CRMs lie within the definition of "measurement standards" or "etalons" given in the VIM.

NOTE 5 Some reference materials (RMs) and CRMs have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement methods. Such materials include certain biological materials such as vaccines to which an International unit has been assigned by the World Health Organization.

[VIM:1993, 6.14]

1.5.13 Client: Any person or organization that engages the services of a testing or calibration laboratory.

1.5.14 Competence: Ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific test and calibration methods.

1.5.15 Deficiency: Nonfulfillment of NVLAP conditions and/or criteria for accreditation; sometimes referred to as a *nonconformance*.

1.5.16 Error (of measurement): Result of a measurement minus a true value of the measurand.

NOTE 1 Since a true value cannot be determined, in practice a conventional true value is used.

NOTE 2 When it is necessary to distinguish "error" from "relative error," the former is sometimes called **absolute error of measurement**. This should not be confused with **absolute value of error**, which is the modulus of the error.

[VIM:1993, 3.10]

1.5.17 Influence quantity: Quantity that is not the measurand but that affects the result of the measurement.

EXAMPLES

temperature of a micrometer used to measure length;

frequency in the measurement of the amplitude of an alternating electric potential difference;

bilirubin concentration in the measurement of hemoglobin concentration in a sample of human blood plasma.

[VIM:1993, 2.7]

1.5.18 Interlaboratory comparisons: Organization, performance and evaluation of tests or calibrations on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

NOTE In some circumstances, one of the laboratories involved in the intercomparison may be the laboratory which provided the assigned value for the test item.

[ISO/IEC Guide 43-1:1997, 3.7 expanded]

1.5.19 Internal audit: Systematic and documented process for obtaining evidence and evaluating it objectively to verify that a laboratory's operations comply with the requirements of its quality system.

1.5.20 Laboratory: Organization that performs tests and/or calibrations. When a laboratory is part of an organization that carries out activities additional to testing and calibration, the term *laboratory* refers only to those parts of that organization that are involved in the testing and calibration process. A laboratory's activities may be carried out at a permanent, temporary, or remote location.

NOTE NVLAP further defines *laboratory* as being a physical entity—that is, a testing or calibration facility that is separate and apart physically from any other laboratory whether or not sharing common ownership, management, or quality systems with any other laboratory(s).

NVLAP previously differentiated between *main facilities* and *sub-facilities*. This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a *sub-facility* may request to be "grandfathered" in its accreditation renewal under the former classification as a *sub-facility*, including the unique conditions associated with that classification.)

1.5.21 Laboratory accreditation body: Body that conducts and administers a laboratory accreditation system and grants accreditation.

1.5.22 Laboratory accreditation system: System that has its own rules of procedure and management for carrying out laboratory accreditation.

1.5.23 LAP: Laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

1.5.24 Limits of permissible error (of a measuring instrument): Extreme values of an error permitted by specifications, regulations, etc. for a given measuring instrument.

[VIM:1993, 5.21]

NOTE This term is frequently referred to as *tolerance* in the United States.

1.5.25 Management review: Formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives.

NOTE 1 Management review may include review of the quality policy.

NOTE 2 Quality audit results are one of the possible inputs to management review.

NOTE 3 The term *top management* refers to the management of the organization whose quality system is being reviewed.

[ISO 8402:1994, 3.9]

1.5.26 Measurand: Particular quantity subject to measurement.

EXAMPLE Vapor pressure of a given sample of water at 20 °C.

NOTE 1 The specification of a measurand may require statements about quantities such as time, temperature and pressure.

[VIM:1993, 2.6]

NOTE 2 As appropriate, this may be the *measured quantity* or the *quantity to be measured*.

1.5.27 Measurement: Set of operations having the object of determining a value of a quantity.

[VIM:1993, 2.1]

1.5.28 Measurement assurance: Process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well-characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts.

1.5.29 Measurement procedure: Set of operations, described specifically, used in the performance of particular measurements according to a given method.

NOTE A measurement procedure is usually recorded in a document that is sometimes itself called a *measurement procedure* (or a *measurement method*) and is usually in sufficient detail to enable an operator to carry out a measurement without additional information.

[VIM:1993, 2.5]

1.5.30 Measuring and test equipment (M & TE): All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a

measurement. This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

NOTE In the context of this handbook, the term *measuring and test equipment* is taken to encompass *measuring instruments* and *measurement standards*. Moreover, a *reference material* is considered to be a type of *measurement standard*.

1.5.31 Measuring instrument: Device intended to be used to make measurements, alone or in conjunction with supplementary device(s).

[VIM:1993, 4.1]

1.5.32 Method of measurement: Logical sequence of operations, described generically, used in the performance of measurements.

NOTE Methods of measurement may be qualified in various ways such as:

— substitution method

— differential method

— null method.

[VIM:1993, 2.4]

1.5.33 NVLAP Lab Code: Unique numeric identifier assigned by NVLAP to each applicant laboratory; e.g., 101000-0. It is used for identification, record-keeping, and data base management, and appears on formal accreditation documents.

1.5.34 Precision: Repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

1.5.35 Proficiency testing (laboratory): Determination of laboratory testing performance by means of interlaboratory comparisons.

[ISO/IEC Guide 2:1996, 13.5]

NOTE For the purposes of this handbook, the term *laboratory proficiency testing* is taken in its widest sense and includes, for example:

a) Qualitative schemes — for example, where laboratories are required to identify a component of a test item.

b) Data transformation exercises — for example, where laboratories are furnished with sets of data and are required to manipulate the data to provide further information.

c) Single item testing — where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.

d) One-off exercises — where laboratories are provided with a test item on a single occasion.

e) Continuous schemes — where laboratories are provided with test items at regular intervals on a continuing basis.

f) Sampling — for example, where individuals or organizations are required to take samples for subsequent analysis.

[ISO/IEC Guide 43-1:1997, 3.6]

1.5.36 Quality manual: Document stating the quality policy and describing the quality system of an organization.

[ISO 8402:1994, 3.12]

1.5.37 Quality system: Organizational structure, procedures, processes, and resources needed to implement quality management.

NOTE 1 The quality system should be as comprehensive as needed to meet the quality objectives.

NOTE 2 The quality system of an organization is designed primarily to satisfy the internal managerial needs of the organization. It is broader than the requirements of a particular customer, who evaluates only the relevant part of the quality system.

NOTE 3 For contractual or mandatory quality assessment purposes, demonstration of the implementation of identified quality system elements may be required.

[ISO 8402:1994, 3.6]

1.5.38 Reference material (RM): Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials.

NOTE A reference material may be in the form of a pure or mixed gas, liquid or solid. Examples are water for the calibration of viscometers, sapphire as a heat-capacity calibrant in calorimetry, and solutions used for calibration in chemical analysis.

[VIM:1993, 6.13]

1.5.39 Reference standard: Standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

[VIM:1993, 6.6]

1.5.40 Requirement: Provision that conveys criteria to be fulfilled.

[ISO/IEC Guide 2:1996, 7.5]

1.5.41 Resolution (of a displaying device): Smallest difference between indications of a displaying device that can be meaningfully distinguished.

NOTE 1 For a digital displaying device, this is the change in the indication when the least significant digit changes by one step.

NOTE 2 This concept applies also to a recording device.

[VIM:1993, 5.12]

1.5.42 Revocation: Removal of the accredited status of a laboratory if the laboratory is found to have violated the terms of its accreditation.

1.5.43 Scope of accreditation: Document issued by NVLAP to a laboratory that lists the test methods or services, or calibration services, for which the laboratory is accredited. A Scope of Accreditation is always accompanied by a Certificate of Accreditation.

1.5.44 Stability: Ability of a measuring instrument to maintain constant its metrological characteristics with time.

NOTE 1 Where stability with respect to a quantity other than time is considered, this should be stated explicitly.

NOTE 2 Stability may be quantified in several ways, for example:

— in terms of the time over which a metrological characteristic changes by a stated amount, or

— in terms of the change in a characteristic over a stated time.

[VIM:1993, 5.14]

1.5.45 Standard, international (measurement): Standard recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned.

[VIM:1993, 6.2]

1.5.46 Standard, measurement: Material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

EXAMPLES

a) 1 kg mass standard;

b) 100 Ω standard resistor;

c) standard ammeter;

d) cesium frequency standard;

e) standard hydrogen electrode;

f) reference solution of cortisol in human serum having a certified concentration.

NOTE 1 A set of similar material measures or measuring instruments that, through their combined use, constitutes a standard is called a collective standard.

NOTE 2 A set of standards of chosen values that, individually or in combination, provides a series of values of quantities of the same kind is called a group standard.

[VIM:1993, 6.1]

1.5.47 Standard, national (measurement): Standard recognized by a national decision to serve, in a country, as the basis for assigning values to other standards of the quantity concerned.

[VIM:1993, 6.3]

1.5.48 Standard, primary: Standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

NOTE The concept of primary standard is equally valid for base quantities and derived quantities.

[VIM:1993, 6.4]

1.5.49 Standard, reference: (See **reference standard**.)

1.5.50 Standard, secondary: Standard whose value is assigned by comparison with a primary standard of the same quantity.

[VIM:1993, 6.5]

1.5.51 Standard, transport (or transfer): Standard used as an intermediary to compare standards.

NOTE The term *transfer device* should be used when the intermediary is not a standard.

[VIM:1993, 6.8]

1.5.52 Standard, working: Standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials.

NOTE 1 A working standard is usually calibrated against a reference standard.

NOTE 2 A working standard used routinely to ensure that measurements are being carried out correctly is called a *check standard*.

[VIM:1993, 6.7]

1.5.53 Sub-facility: Laboratory operating under the technical direction and quality system of an accredited main facility. (See note under **laboratory**.)

1.5.54 Suspension: Temporary removal of the accredited status of a laboratory when the laboratory is found to be out of compliance with the terms of its accreditation.

1.5.55 Test: Technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure.

[ISO/IEC Guide 2:1996, 13.1]

1.5.56 Test method: Specified technical procedure for performing a test.

[ISO/IEC Guide 2:1996, 13.2]

1.5.57 Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

NOTE 1 The concept is often expressed by the adjective *traceable*.

NOTE 2 The unbroken chain of comparisons is called a *traceability chain*.

[VIM:1993, 6.10]

1.5.58 Uncertainty of measurement: Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

NOTE 1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

NOTE 2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

NOTE 3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

This definition is that of the *Guide to the expression of uncertainty in measurement* in which its rationale is detailed (see, in particular, 2.2.4 and annex D[10]).

[VIM:1993, 3.9]

1.5.59 Uncertainty, Type A (evaluation of): Method of evaluation of uncertainty by the statistical analysis of series of observations.

[GUM:1993, 2.3.2]

1.5.60 Uncertainty, Type B (evaluation of): Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

[GUM:1993, 2.3.3]

1.5.61 Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

NOTE 1 In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirements for that activity.

NOTE 2 The term *verified* is used to designate the corresponding status.

[ISO 8402:1994, 2.17]

NOTE 3 In the United States,verification is frequently referred to as *calibration*.

1.6 NVLAP publications

NVLAP publishes a variety of documents in paper and electronic formats for use by testing and calibration laboratories and others needing information about the NVLAP program. Accredited and applicant laboratories are routinely sent new and revised NVLAP publications. Many of these publications are available on the NVLAP web site, <www.nist.gov/nvlap>.

1.6.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*

This handbook sets forth the procedures under which NVLAP operates and the general requirements for accreditation as prescribed in Title 15 of the U.S. Code of Federal Regulations, Part 285 — the primary document describing the legal basis for NVLAP. Sections 4 and 5 of the handbook include all requirements of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. Annexes A and B contain additional requirements specific to NVLAP.

1.6.2 NIST Handbook 150 series (program-specific handbooks)

This series of handbooks contains guidance, interpretive information, and technical requirements for the LAPs. A separate handbook is published for each LAP or unique field of testing or calibration, and tailors the general criteria in NIST Handbook 150 to the specific tests, calibrations, or types of tests or calibrations covered by a LAP. A program-specific handbook(s) and NIST Handbook 150 constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation.

1.6.3 NIST Special Publication 810, *NVLAP Directory*

This publication is updated annually and lists the following information for each accredited laboratory: NVLAP Lab Code, laboratory name and address, Authorized Representative, phone and fax numbers, e-mail and URL addresses (if available), accreditation expiration date, and scope of accreditation. The directory is distributed worldwide to participating laboratories, manufacturers, suppliers, retailers, professional and trade associations, standards groups, and government agencies.

The NVLAP web site, <www.nist.gov/nvlap>, also includes a listing of NVLAP-accredited laboratories; it is updated on a periodic basis.

1.6.4 Other publications

NVLAP may publish other documents from time to time, as necessary to ensure communication of program information to laboratories and interested parties, such as policy guides, laboratory bulletins, technical briefs, and newsletters.

1.7 Confidentiality

To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.

1.8 Referencing NVLAP accreditation (see also Annex A)

1.8.1 The term *NVLAP* (represented by the NVLAP logo) is a federally registered certification mark of the National Institute of Standards and Technology and the federal government, who retain exclusive rights to control the use thereof. Permission to use the term and/or logo is granted to NVLAP-accredited laboratories for the limited purposes of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NIST reserves the right to control the quality of the use of the term *NVLAP* and of the logo itself.

1.8.2 NVLAP's policy is to control the use of the term and logo and to ensure that accredited laboratories express their accredited status in a manner that is clear and accurate, and not misleading. This policy applies to test and calibration reports, letterheads, contracts, business cards, brochures, advertising, web sites, and any other use not specified herein.

1.8.3 NVLAP-accredited laboratories are authorized to use the term and logo to reference their accredited status, subject to the conditions presented in Annex A. Failure to comply with the conditions may result in suspension or revocation of a laboratory's accreditation.

1.8.4. Use of the term and logo by other persons and organizations shall be authorized in writing by NVLAP on a case-by-case basis.

1.8.5 Photographic and electronic copies of the logo are available from NVLAP upon request.

1.8.6 Use of the term and logo by a laboratory whose status is suspended, revoked, or voluntarily terminated is specified in 3.9, 3.10, and 3.11.

1.9 Mutual recognition

Consistent with applicable laws and regulations, the Director of NIST may negotiate and conclude agreements for NVLAP with other laboratory accreditation entities. These agreements, realized through Mutual Recognition Arrangements (MRAs), serve to support trade facilitation activities and promote harmonization of laboratory accreditation criteria. At a minimum, any agreement must provide that accredited laboratories of other accreditation bodies meet conditions for accreditation comparable to and consistent with those set out in this handbook.

1.10 Information collection requirements

The information collection requirements contained in these procedures have been approved by the Office of Management and Budget under the Paperwork Reduction Act and have been assigned OMB control number 0693-0003.

2 LAP establishment, development and implementation

2.1 Bases for establishment

NVLAP establishes LAPs in response to legislative or administrative actions or to requests from private sector entities and government agencies.

2.1.1 LAPs established through legislative or administrative actions

Upon receipt of a mandate for a LAP based on legislative or administrative action, the Chief of NVLAP shall publish a *Federal Register* notice:

a) stating the purpose of the LAP, including the national or international need;

b) describing the general scope of the LAP;

c) identifying government agencies having oversight; and

d) providing information to any interested party wishing to receive routine information on the development of the LAP.

2.1.2 LAPs established by request

2.1.2.1 A request to establish a LAP must be made in writing to the Chief of NVLAP. Each request must include:

a) the scope of the LAP in terms of products, testing services, or calibration services proposed for inclusion;

b) specific identification of the applicable standards and test methods, including appropriate designations, and the organizations or standards-writing bodies having responsibility for them;

c) a statement of the perceived need for the LAP including:

   — technical and economic reasons why the LAP would benefit the public interest;

   — evidence of a national need to accredit testing or calibration laboratories for the specific scope beyond that served by an existing laboratory accreditation program in the public or private sector;

   — an estimate of the number of laboratories that are likely to seek accreditation; and

   — an estimate of the number and nature of the users of such laboratories; and

d) a statement of the extent to which the requestor is willing to support necessary developmental aspects of the LAP with funding and personnel.

2.1.2.2 If the requestor is a private sector entity, then the request must include a description of the ways in which the following conditions have been met:

a) public notice of meetings and other activities related to the LAP request is provided in a timely fashion and is distributed in a manner designed to reach the attention of interested persons;

b) meetings are open and participation in activities is available to interested persons;

c) decisions reached by the private sector entity in the development of a request for a LAP represent substantial agreement of the interested persons;

d) prompt consideration is given to the expressed views and concerns of interested persons;

e) adequate and impartial mechanisms for handling substantive and procedural complaints and appeals are in place; and

f) appropriate records of all meetings are maintained and the official procedures used by the private sector entity to make a formal request for a LAP are made available upon request to any interested person.

2.1.2.3 If the requestor is a federal, state, or local government agency, then the request must include a description of the procedures followed or a citation of the specific authority used to identify a need for the LAP. For state and local government agencies, the request must also include a statement explaining why the LAP should be of national scope.

2.1.2.4 NVLAP may request clarification of the information submitted in the request.

2.1.2.5 The Chief of NVLAP shall analyze the request and any supporting information received, and after consultation with interested parties through public workshops and other means, shall determine if there is need for the requested LAP. In making this determination, the Chief of NVLAP shall consider the following:

a) the needs and scope of the LAP requested;

b) the needs and scope of the user population;

c) the nature and content of other relevant public and private sector laboratory accreditation programs;

d) compatibility with the criteria referenced in Section 4 and Section 5;

e) the importance of the requested LAP to commerce, consumer well-being, or the public health and safety; and

f) the economic and technical feasibility of accrediting laboratories for the tests or calibrations, types of tests or calibrations, or standards requested.

2.1.2.6 The Chief of NVLAP shall make the decision to either:

a) develop the LAP, if a need has been demonstrated and resources are available for the LAP's development;

b) defer development of the LAP until resources become available, if a need has been demonstrated and there are no resources for development; or

c) not develop the LAP, if a need has not been demonstrated.

2.1.2.7 The Chief of NVLAP shall inform the requestor and other interested parties of the LAP decision.

2.2 Development of technical requirements

2.2.1 Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in Section 4 and Section 5 to the tests or calibrations, types of tests or calibrations, or standards covered by the LAP.

2.2.2 NVLAP shall develop the technical requirements based on relevant and impartial expert advice. This advice may be obtained through one or more public workshops or other suitable means.

2.2.3 NVLAP shall make every reasonable effort to ensure that the affected testing or calibration community within the scope of the LAP is informed of any planned workshop. A summary of each workshop shall be prepared and made available upon request.

2.3 Coordination with federal agencies

As a means of ensuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by established LAPs, NVLAP shall communicate and consult with appropriate officials within those agencies.

2.4 Announcing the establishment of a LAP

When NVLAP has completed the development of the technical requirements, it shall publish a notice in the *Federal Register* announcing the establishment of the LAP. The notice will identify the scope of the LAP and advise laboratories how to apply for accreditation.

2.5 Adding to or modifying a LAP

2.5.1 A LAP may be added to, modified, or realigned based on either a written request or a need identified by NIST. Any person wishing to add or delete specific tests or calibrations, types of tests or calibrations, or standards may submit a request to NVLAP.

2.5.2 NVLAP may choose to make the additions or modifications available for accreditation under a LAP when:

a) the additional tests or calibrations, types of tests or calibrations, or standards requested are directly relevant to the LAP;

b) it is feasible and practical to accredit testing or calibration laboratories for the additional tests or calibrations, types of tests or calibrations, or standards; and

c) it is likely that laboratories will seek accreditation for the additional tests or calibrations, types of tests or calibrations, or standards.

2.6 Termination of a LAP

2.6.1 The Chief of NVLAP may terminate a LAP when he/she determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Chief of NVLAP proposes to terminate a LAP, a notice will be published in the *Federal Register* setting forth the basis for that determination.

2.6.2 When a LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP. Technical expertise will be maintained by NVLAP while any accreditation remains effective.

3 Accreditation process

3.1 Application for accreditation

3.1.1 Required information

3.1.1.1 A laboratory may apply for accreditation in any of the established LAPs. The applicant laboratory shall provide a completed application to NVLAP, pay all required fees, agree to conditions for accreditation, and provide a quality manual to NVLAP (or a designated NVLAP assessor) prior to the assessment process.

3.1.1.2 Required information for accreditation includes, but is not limited to:

a) legal name and full address of the laboratory;

b) ownership of the laboratory;

c) Authorized Representative's name and contact information;

d) names, titles and contact information for laboratory staff nominated to serve as Approved Signatories of test or calibration reports that reference NVLAP accreditation;

e) organization chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;

f) general description of the laboratory, including its facilities and scope of operation; and

g) requested scope of accreditation.

3.1.1.3 The General Application shall be signed by the laboratory's Authorized Representative, who commits the laboratory to comply with the conditions of accreditation (see 3.1.2) and with the requirements contained in sections 4 and 5 of this handbook. Before signing the application, the Authorized Representative should review all documents provided with the application package and become familiar with NVLAP requirements. Only the Authorized Representative can authorize a change in the scope or nature of a laboratory's application.

3.1.1.4 The laboratory shall provide a copy of its quality manual and related documentation, where appropriate, prior to the on-site assessment. NVLAP will review the quality system documentation and discuss any noted deficiencies with the Authorized Representative before the assessment is performed.

3.1.2 Conditions for accreditation

To become accredited and maintain accreditation, a laboratory shall agree in writing to:

a) comply at all times with the NVLAP criteria for accreditation as set forth in this handbook and relevant technical documents;

b) fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

c) participate in proficiency testing as required;

d) follow NVLAP conditions for referencing accreditation status (see Annex A);

e) resolve all deficiencies;

f) report to NVLAP within thirty days any major changes that affect the laboratory's:

- legal, commercial, organizational, or ownership status;
- organization and management; e.g., key managerial staff;
- policies or procedures, where appropriate;
- location;
- personnel, equipment, facilities, working environment or other resources, where significant;
- Authorized Representative or Approved Signatories; or
- other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements of this handbook and relevant technical documents;

g) return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it be requested to do so by NVLAP.

3.1.3 Fees for accreditation

3.1.3.1 General

NVLAP operates on a cost-reimbursable basis from fees paid by participating laboratories that apply for accreditation in specific NVLAP fields of testing or calibration. For fee calculation purposes, a field is considered to be any area of accreditation that is a separate line item on the NVLAP Fee Schedule.

3.1.3.2 Fee structure

The fee structure is reviewed annually and revised, as necessary. The current structure incorporates four major fee categories:

a) The *Initial Application Fee* covers costs associated with processing an applicant for the first time. It is paid only one time per laboratory and is due with the initial application for accreditation.

b) The *Administrative/Technical Support Fee* covers costs associated with NVLAP and other NIST staff conducting the program in all areas for which accreditation is offered and for providing these services to participating laboratories. A discount is available if multiple fields of accreditation are selected by a laboratory.

   This fee is due annually regardless of the accreditation status of a laboratory. Laboratories that have been enrolled in a program for more than one year and are not yet accredited will be invoiced annually for the Administrative/Technical Support Fee, based on the date the laboratory's initial application was accepted by NVLAP.

c) The *On-Site Assessment Fee* covers costs incurred for on-site assessment visits and is due only for a year in which an assessment is scheduled.

   NOTE The optional use of a preassessment visit will be considered if it is decided that such a visit would result in a better definition of the scope of accreditation which has been requested by the laboratory. In such cases, the preassessment costs will be charged to the laboratory in addition to the actual On-Site Assessment Fee.

   A laboratory will be charged for an additional assessment visit if required as the result of deficiencies in meeting NVLAP criteria. The fee for this additional assessment visit is the same as the On-Site Assessment Fee on the NVLAP Fee Schedule.

   A laboratory will not be charged separately for a monitoring visit, which may be initiated by NVLAP at any time during the accreditation period for cause or on a random selection basis (see 3.8).

d) The *Proficiency Testing Fee* covers costs relating to the provision of proficiency test samples and artifacts, the collection and analysis of laboratory results, and reports to NVLAP. Laboratories participating in required proficiency testing not covered by initial or renewal accreditation fees will be invoiced.

3.1.3.3 Fee refund policy

3.1.3.3.1 This refund policy applies to laboratories that withdraw from the NVLAP program.

3.1.3.3.2 The *Initial Application Fee* is nonrefundable.

3.1.3.3.3 The amount of the *Administrative/Technical Support Fee* to be refunded depends upon the length of time that has elapsed between the laboratory's renewal date and the date NVLAP was notified of the decision to withdraw (see table 1). If a laboratory is seeking initial accreditation (i.e., has never been accredited for a specific program), the time of withdrawal will be counted as the number of months after the date the initial application was received.

Table 1. Amount of Administrative/Technical Support Fee Refund

Time of withdrawal (# of months)	*Refund amount*
Less than 3 months	3/4
3 months to less than 6 months	1/2
6 months to less than 9 months	1/4
9 months or greater	No refund

3.1.3.3.4 The *On-Site Assessment Fee* is refundable only if no on-site related costs have been incurred. Otherwise, costs incurred will be deducted from the *On-Site Assessment Fee*.

3.1.3.3.5 The portion of the *Proficiency Testing Fee* for any proficiency testing planned but not sent to the laboratory, or for any proficiency testing that was not initiated, will be refunded. No refund will be given for artifacts sent but returned unmeasured by the laboratory.

3.1.4 Receipt of application

3.1.4.1 Upon receipt of a laboratory's application for accreditation, NVLAP shall:

a) assign a NVLAP Lab Code to the applicant laboratory;

b) acknowledge receipt of the application in writing;

c) request further information, if necessary;

d) confirm payment of fees before proceeding with the assessment process; and

e) specify the next step(s) in the accreditation process.

3.1.4.2 The information received shall be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality (see 1.7).

3.1.5 Laboratories located outside of the United States

3.1.5.1 In cases where laboratory documents are not in English, or laboratory personnel do not speak English, it is the responsibility of the laboratory to provide an interpreter(s), subject to NVLAP approval, to assist the NVLAP assessor(s) during the on-site assessment. The interpreter will assist the assessor(s) with conversing directly with laboratory management and technical staff and with reviewing laboratory documentation. Documents such as quality manuals, procedures, standards, and test reports sent to NVLAP prior to on-site assessments or reviewed during assessments may be required to be provided in English to verify compliance with NVLAP requirements.

3.1.5.2 Some of the fees listed on the NVLAP Fee Schedule may be insufficient to cover the costs incurred by an applicant laboratory located outside of the United States. In such cases, the laboratory will be responsible for all additional costs incurred. Additional fees will be charged, if necessary, for travel by NVLAP assessor(s) outside the United States, for shipment of proficiency testing materials to the laboratories, and for any additional administrative expenses. To ensure that the initial or renewal application is processed without delay, payment (in U.S. currency) of the appropriate listed fees should accompany the application. When all the additional costs associated with the application have been identified, an invoice for any additional fee amount owed will be sent to the laboratory.

3.1.5.3 Pursuant to U.S. Department of Commerce Export Regulations and/or U.S. Department of State International Traffic in Arms Regulations, certain technologies, equipment, data and software may not be exported from the United States to certain foreign destinations without first obtaining an export license or official approval. If a laboratory uses such technologies, NVLAP requires that the laboratory possess, and show upon request, the appropriate license or official U.S. Government approval. For export and license information for the Department of Commerce's regulations, contact the Bureau of Export Administration, Washington, DC, telephone 202-482-4811, fax 202-482-3617, or see the Bureau's web site <http://www.bxa.doc.gov>. For export and license information regarding the State Department's International Traffic in Arms Regulations, please contact the Department of State, telephone 202-663-2980, or see the Department's Defense Trade Controls web site <http://www.pmdtc.org>.

3.2 Assessment

3.2.1 Frequency and scheduling

3.2.1.1 Before initial accreditation, during the first renewal year, and every two years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria.

3.2.1.2 After payment of the required fees, the laboratory will be contacted to schedule a mutually acceptable date for the on-site assessment.

3.2.1.3 An assessment normally takes one to five days depending on the scope of the laboratory's application. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory.

3.2.2 Assessors

3.2.2.1 NVLAP shall select qualified assessors to evaluate all information collected from an applicant laboratory and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

3.2.2.2 Assessors are selected on the basis of their professional and academic achievements, experience in the field of testing or calibration, management experience, training, technical knowledge, and communications skills. For example, they may be engineers or scientists currently active in the field, consultants, or college professors.

3.2.2.3 An assessor is assigned to conduct an on-site assessment of a particular laboratory on the basis of how well his or her experience matches the type of testing or calibration to be assessed, as well as the absence of conflict of interest. NVLAP provides the laboratory with a short biographical sketch of the assessor(s). A lead assessor will be assigned if needed. A laboratory may request an alternate assessor if a conflict of interest or prior business relationship exists.

3.2.3 Conduct of assessment

3.2.3.1 Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others.

3.2.3.2 During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of testing or calibrations, and examines tests or calibration reports.

3.2.3.3 The assessor reviews laboratory records, including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the testing or calibration for which accreditation is sought. The assessor need not be given information which violates individual privacy, such as salary, medical information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or in separate folders that contain only the information that the NVLAP assessor needs to review.

3.2.3.4 At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any deficiencies with the Authorized Representative and other responsible laboratory staff.

3.2.4 Assessment report

3.2.4.1 At the exit briefing, the assessor submits a written report on the compliance of the laboratory with the accreditation requirements, together with the completed checklists, where appropriate. The report shall include as a minimum:

a) date(s) of assessment;

b) the names of the assessor(s) responsible for the report;

c) the names and addresses of all the laboratory sites assessed;

d) the assessed scope of accreditation or reference thereto; and

e) comments and/or deficiencies cited by the assessor(s) on the compliance of the laboratory with the accreditation requirements.

3.2.4.2 The report must be signed by the laboratory's Authorized Representative to acknowledge the discussion and receipt of the report.

3.2.4.3 The assessor forwards the original report to NVLAP and leaves a copy with the laboratory.

3.2.5 Deficiency notification and resolution

3.2.5.1 Laboratories are informed of deficiencies during the on-site assessment, and deficiencies are documented in the assessment report (3.2.4.1e).

3.2.5.2 A laboratory shall respond in writing to NVLAP within thirty days of the date of the assessment report. The response shall be signed by the Authorized Representative and include documentation that the specified deficiencies have either been corrected and/or a plan of corrective actions. A corrective action plan must include a list of actions, target completion dates, and names of persons responsible for discharging those actions.

3.2.5.3 If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and evaluation prior to an accreditation decision (see 3.4).

3.2.5.4 An on-site assessment review is conducted after a laboratory has undergone an on-site assessment, whether or not deficiencies are found, to determine if the laboratory has met all of the on-site assessment requirements.

3.3 Proficiency testing

3.3.1 General

3.3.1.1 Proficiency testing is an integral part of the NVLAP accreditation process. The performance of tests or calibrations and reporting of results from proficiency testing assists NVLAP in determining the overall effectiveness of the laboratory. Information obtained from proficiency testing helps to identify problems in a laboratory; if problems are found, NVLAP works with the laboratory staff to solve them.

3.3.1.2 NVLAP proficiency testing is consistent with the provisions contained in ISO/IEC Guide 43: 1997 (Parts 1 and 2), where applicable. Proficiency testing may be organized by NVLAP itself or by a NVLAP-approved provider of services.

3.3.2 Types of proficiency testing

Proficiency testing requirements are associated with most fields of accreditation. Proficiency testing techniques vary depending on the nature of the test item, the method in use, and the number of laboratories participating.

3.3.2.1. Proficiency testing using *interlaboratory* comparisons may utilize randomly selected specimens from a batch of uniform material, selected specimens with known properties and results, artifacts with similar properties that have not been characterized, and one-of-a-kind artifacts.

3.3.2.2 Proficiency testing may use such *intralaboratory* techniques as comparisons of computer software implementations to reference implementations, use of standard reference materials, and use of fundamental physical laws.

3.3.2.3 Proficiency testing for calibration laboratories may involve comparison of the results of measurements made by the laboratory on selected instruments or artifacts with calibration results obtained independently by NIST/NVLAP.

3.3.3 Analysis and reporting

Proficiency testing data are analyzed by NVLAP and the participants' own results are reported to them. Summary results are available upon request to other interested parties; e.g., professional societies and standards writing bodies. The identity and performance of individual laboratories are kept confidential.

3.3.4 Proficiency testing deficiencies

3.3.4.1 Unsatisfactory participation in any NVLAP proficiency testing program is a technical deficiency which must be resolved in order to obtain initial accreditation or maintain accreditation.

3.3.4.2 Proficiency testing deficiencies are defined as, but not limited to, one or more of the following:

a) failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

b) failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials;

c) failure to submit laboratory control data as required; and

d) failure to produce acceptable test or calibration results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

3.3.4.3 NVLAP will notify the laboratory of proficiency testing deficiencies and actions to be taken to resolve the deficiencies. Denial or suspension of accreditation will result from failure to resolve deficiencies.

3.4 Accreditation decision

3.4.1 The Chief of NVLAP is responsible for all NVLAP accreditation actions, including granting, renewing, suspending, and revoking any NVLAP accreditation.

3.4.2 The accreditation decision is based on NVLAP review of information gathered during the accreditation process and a determination of whether or not all requirements for accreditation have been fulfilled.

3.4.3 The evaluation process considers the laboratory's record as a whole, including:

a) information provided on the application;

b) results of quality system documentation review;

c) on-site assessment reports;

d) actions taken by the laboratory to correct deficiencies; and

e) results of proficiency testing, if required.

3.4.4 Based on this evaluation, NVLAP determines whether or not a laboratory should be accredited. If the evaluation reveals deficiencies, NVLAP shall inform the laboratory in writing of the deficiencies, and the laboratory must respond as specified in 3.2.5. All deficiencies must be resolved to NVLAP's satisfaction before accreditation can be granted.

3.5 Granting accreditation

3.5.1 Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four accreditation renewal dates (January 1, April 1, July 1, or October 1) is assigned to the laboratory and is usually retained as long as the laboratory remains in the program. The renewal period is one year; accreditation expires and is renewable on the assigned date.

3.5.2 Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.

3.5.3 When accreditation is granted, NVLAP shall provide to the laboratory a Certificate of Accreditation and a Scope of Accreditation, which permit identification of:

a) the name and address of the laboratory that has been accredited;

b) the scope of the accreditation, including:

- the tests or calibrations, or types of tests or calibrations, for which accreditation has been granted;
- for calibrations, the type of measurement performed, the measurement range, and best measurement uncertainty;
- for tests, the materials or products tested, the methods used, and the tests performed;
- for specific tests and calibrations for which accreditation has been granted, the methods used defined by written standards or reference documents that have been accepted by the accreditation body;

c) the laboratory's Authorized Representative;

d) the expiration date of the accreditation; and

e) the NVLAP Lab Code.

3.6 Renewal of accreditation

3.6.1 Each accredited laboratory shall be sent a renewal application package before the expiration date of its accreditation to allow sufficient time to complete the renewal process.

3.6.2 Fees for renewal are charged according to services required as listed on the NVLAP Fee Schedule.

3.6.3 Both the application and fees must be received by NVLAP prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

3.6.4 On-site assessments of currently accredited laboratories are performed in accordance with the procedures in 3.2. If deficiencies are found during the assessment of an accredited laboratory, the laboratory must submit a satisfactory response concerning resolution of deficiencies within thirty days of notification or face possible suspension or revocation of accreditation.

3.6.5 Undue delay in the resolution of deficiencies may necessitate another on-site assessment at additional cost to the laboratory.

3.7 Changes to scope of accreditation

A laboratory may request in writing changes to its Scope of Accreditation. If the laboratory requests additions to its Scope, it must meet all NVLAP criteria for the additional tests or calibrations, types of tests or calibrations, or standards. The need for an additional on-site assessment and/or proficiency testing will be determined on a case-by-case basis.

3.8 Monitoring visits

3.8.1 In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

3.8.2 The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review deficiency resolutions, verify reported changes in the laboratory's personnel, facilities, or operations, or administer proficiency testing, when appropriate.

3.9 Suspension of accreditation

3.9.1 If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation (see 3.10). The determination by NVLAP whether to suspend the laboratory or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

3.9.2 If a laboratory's accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated. A reassessment of the laboratory may also be required for reinstatement. Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports, correspondence, or advertising during the suspension period in the area(s) affected by the suspension.

3.9.3 NVLAP will not require a suspended laboratory to return its Certificate and Scope of Accreditation, but the laboratory must refrain from using the NVLAP logo in the area(s) affected until such time as the problem(s) leading to the suspension has been resolved. When accreditation is reinstated, NVLAP will authorize the laboratory to resume testing or calibration activities in the previously suspended area(s) as an accredited laboratory.

3.10 Denial and revocation of accreditation

3.10.1 If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

3.10.2 The laboratory will have thirty days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the thirty-day period.

3.10.3 If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation (see 3.11).

3.10.4 A laboratory whose accreditation has been revoked must cease use of the NVLAP logo on any of its reports, correspondence, or advertising related to the area(s) affected by the revocation. If the revocation is total, NVLAP will instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP logo from all test or calibration reports, correspondence, or advertising. If the revocation affects only some, but not all of the items listed on a laboratory's Scope of Accreditation, NVLAP will issue a revised Scope that excludes the revoked area(s) in order that the laboratory might continue operations in accredited areas.

3.10.5 A laboratory whose accreditation has been denied or revoked, may reapply (see 3.1) and be accredited if the laboratory:

a) completes the assessment and evaluation process; and

b) meets the NVLAP conditions and criteria for accreditation.

3.11 Voluntary termination of accreditation

3.11.1 A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so.

3.11.2 Upon receipt of a request for termination, NVLAP shall terminate the laboratory's accreditation, notify the laboratory that its accreditation has been terminated, and instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP logo from all test and calibration reports, correspondence, and advertising.

3.11.3 A laboratory whose accreditation has been voluntarily terminated may reapply (see 3.1) and be accredited if the laboratory:

a) completes the assessment and evaluation process; and

b) meets the NVLAP conditions and criteria for accreditation.

4 Management requirements for accreditation

4.1 Organization

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this handbook and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this handbook.

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) appoint deputies for key managerial personnel (see note).

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.2 Quality system

4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients;

b) the management's statement of the laboratory's standard of service;

c) the objectives of the quality system;

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) the laboratory management's commitment to compliance with this handbook.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and clients' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.

4.2.4 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this handbook, shall be defined in the quality manual.

4.3 Document control

4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.12.

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be formally reissued as soon as practicable.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2).

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client.

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal clients, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a client with testing and/or calibration services.

4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

NOTE For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

4.4.4 The client shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of tests and calibrations

4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this handbook for the work in question.

4.5.2 The laboratory shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing.

4.5.3 The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this handbook for the work in question.

4.6 Purchasing services and supplies

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

4.7 Service to the client

The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

NOTE 1 Such cooperation may include:

a) providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes.

NOTE 2 Clients value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g., client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).

4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the client is notified and work is recalled;

e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 shall be promptly followed.

4.10 Corrective action

4.10.1 General

The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

NOTE A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from clients or staff observations.

4.10.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include client requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.10.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.10.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.10.5 Additional audits

Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.11 Preventive action

4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

4.12 Control of records

4.12.1 General

4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE Records may be in any media, such as hard copy or electronic media.

4.12.1.3 All records shall be held secure and in confidence.

4.12.1.4 The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.12.2 Technical records

4.12.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and feedback.

4.12.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

4.13 Internal audits

4.13.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the

requirements of the quality system and this handbook. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE The cycle for internal auditing should normally be completed in one year.

4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.14 Management reviews

4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

— the suitability of policies and procedures;

— reports from managerial and supervisory personnel;

— the outcome of recent internal audits;

— corrective and preventive actions;

— assessments by external bodies;

— the results of interlaboratory comparisons or proficiency tests;

— changes in the volume and type of the work;

— client feedback;

— complaints;

— other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

5 Technical requirements for accreditation

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

— human factors (5.2);

— accommodation and environmental conditions (5.3);

— test and calibration methods and method validation (5.4);

— equipment (5.5);

— measurement traceability (5.6 and Annex B);

— sampling (5.7);

— the handling of test and calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE 1 In some technical areas (e.g., nondestructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the client.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

— relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;

— knowledge of the general requirements expressed in the legislation and standards; and

— an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc., concerned.

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.

5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

— the responsibilities with respect to performing tests and/or calibrations;

— the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;

— the responsibilities for reporting opinions and interpretations;

— the responsibilities with respect to method modification and development and validation of new methods;

— expertise and experience required;

— qualifications and training programs;

— managerial duties.

5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

NVLAP Note: This requirement also applies to Approved Signatories (see 1.5.4).

5.3 Accommodation and environmental conditions

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.4 Test and calibration methods and method validation

5.4.1 General

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including

- affixing of identification marks, handling, transporting, storing and preparation of items,
- checks to be made before the work is started,
- checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
- the method of recording the observations and results,
- any safety measures to be observed;

i) criteria and/or requirements for approval/rejection;

j) data to be recorded and method of analysis and presentation;

k) the uncertainty or the procedure for estimating uncertainty.

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or

reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the client are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

— the requirements of the test method;

— the requirements of the client;

— the existence of narrow limits on which decisions on conformance to a specification are based.

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

NVLAP Note: ANSI/NCSL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM).

5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2a).

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this handbook are met.

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

a) the identity of the item of equipment and its software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 5.5.2);

d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

g) the maintenance plan, where appropriate, and maintenance carried out to date;

h) any damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.

5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

5.6 Measurement traceability

5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.

NOTE Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

NVLAP Note: See Annex B for requirements for the implementation of traceability policy in NVLAP-accredited laboratories.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

— the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

— the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of interlaboratory comparisons is required where possible.

5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules

5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

5.7 Sampling

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all

documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.8 Handling of test and calibration items

5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client.

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the quality of test and calibration results

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programs;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

5.10 Reporting the results

5.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this handbook are met.

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

a) a title (e.g., "Test Report" or "Calibration Certificate");

b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) the name and address of the client;

e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;

h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

i) the test or calibration results with, where appropriate, the units of measurement;

j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

NVLAP Note: NVLAP defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory (see 1.5.4).

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results,

when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;

d) where appropriate and needed, opinions and interpretations (see 5.10.5);

e) additional information which may be required by specific methods, clients or groups of clients.

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

a) the date of sampling;

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and procedures used;

e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).

5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

— an opinion on the statement of compliance/noncompliance of the results with requirements;

— fulfilment of contractual requirements;

— recommendations on how to use the results;

— guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this handbook shall be met (see also 5.4.7).

5.10.8 Format of reports and certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

> "Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified],"

or an equivalent form of wording.

Such amendments shall meet all the requirements of this handbook.

When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Annex A (normative)

Referencing NVLAP accreditation

The following conditions, which pertain to the use of the term *NVLAP* and the NVLAP logo, shall be met by a laboratory in order to become and remain accredited. Failure to comply with these conditions may result in suspension or revocation of a laboratory's accreditation.

a) The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP logo.

b) The term and logo shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.

c) When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.

d) Reference to the NVLAP Lab Code by an applicant laboratory that has not yet achieved accreditation shall include a statement accurately reflecting the laboratory's status.

e) When the NVLAP logo is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code in an approved caption. The caption shall appear below and in close proximity to the logo. The following captions have been approved by NVLAP:

- "For the scope of accreditation under NVLAP Lab Code 000000-0" (fig. 1)
- "NVLAP Lab Code 000000-0" (fig. 2).

f) The form of the NVLAP logo must conform to the following guidelines:

- The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.
- The aspect ratio (height to width) shall be 1 to 2.25 (fig. 3).
- The logo and caption shall be of a size that allows the caption to be easily read. The size of the caption shall not exceed the size of the logo itself.
- The logo shall appear in black, blue, or other color approved by NVLAP, and may be filled or unfilled. In the case of a filled logo, the same color shall be used for the outline and the fill.

g) The name of at least one Approved Signatory shall appear on a test or calibration report that displays the NVLAP logo or references NVLAP accreditation. A computer-generated report may have the Approved Signatory's name printed along with the test or calibration results, as long as there is evidence that there is a system in place to ensure that the report cannot be generated without the review and consent of the Approved Signatory. There may be legal or contractual requirements for original signatures to appear on the report.

h) When the term and logo are used on test or calibration reports, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

A test or calibration report that contains both data covered by the accreditation and data not covered by the accreditation shall clearly identify the data that are not covered by the accreditation. The report must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the NVLAP accreditation."

i) When the term and logo are used on test or calibration reports that also include work done by subcontracted laboratories, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

A test or calibration report that contains both data covered by the accreditation and data provided by a subcontractor shall clearly identify the data that were provided by the subcontracted laboratory. The report must prominently display the following statement at the beginning of the report: "This report contains data that were produced under subcontract by Laboratory X." If the subcontracted laboratory is accredited by NVLAP, then its Lab Code should also be stated. If the subcontracted laboratory is accredited by a body other than NVLAP, then the name of the accreditation body and the laboratory's number or other unique identifier should also be stated. If the subcontracted laboratory is not accredited, then this must be stated.

j) Each test and calibration report bearing the term or logo shall include a statement that the report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government.

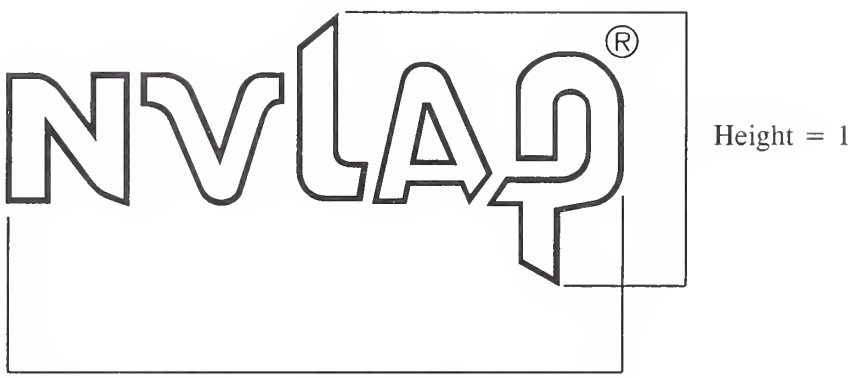
k) When used in a contract or proposal, the term and logo shall be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.

FOR THE SCOPE OF ACCREDITATION UNDER NVLAP LAB CODE 000000-0

Figure 1. NVLAP Logo and caption 1.

NVLAP LAB CODE 000000-0

Figure 2. NVLAP Logo and caption 2.



Width = 2.25 (does not include registration mark)

Aspect Ratio of 2.25:1

Figure 3. Aspect ratio of the NVLAP logo (width to height).

Annex B (normative)

Implementation of traceability policy in accredited laboratories

It is a fundamental requirement that the results of all accredited calibrations and the results of all calibrations required to support accredited tests shall be traceable to national and international standards of measurement. NIST Handbook 150 (and ISO/IEC 17025) details the specific requirements for traceability to be met by testing and calibration laboratories. This annex provides guidance as to how these requirements may be met and how traceability of measurement can be assured by an accredited laboratory.

B.1 General

Laboratories shall be able to demonstrate proper use of traceable standards and test and measurement equipment by competent laboratory personnel in a suitable environment in performing the tests for which accreditation is desired or held. This demonstration will include the determination of the appropriate measurement uncertainty.

Calibration certificates received by NVLAP-accredited testing and calibration laboratories with new or recalibrated equipment shall meet the requirements of ISO/IEC 17025. The certificates must include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

B.2 Demonstration of traceability

B.2.1 NVLAP-accredited laboratories may submit appropriate physical standards and test and measurement equipment directly to NIST or, when appropriate, to another national metrology institute. Accredited laboratories may obtain certified reference materials from NIST (called Standard Reference Materials under copyright) or from another national metrology institute. Use of a national metrology institute other than NIST shall be documented and will be assessed by NVLAP.

B.2.2 Testing laboratories that perform calibrations only for themselves do not need to be accredited as calibration laboratories. Calibration laboratories that perform specific calibrations only for themselves to support their accredited services do not need to be accredited for those calibrations. For the purpose of assuring traceability, an accredited laboratory may calibrate its own equipment if the appropriate requirements of NIST Handbook 150 have been met.

B.2.3 NVLAP-accredited laboratories that do not demonstrate traceability as described in B.2.1 or B.2.2, shall use accredited calibration laboratory services wherever available. Accredited calibration laboratories are those accredited by NVLAP or by any accrediting body with which NVLAP has a mutual recognition arrangement. A listing of NVLAP-accredited calibration laboratories and of accreditation bodies with which NVLAP currently has agreements is available from NVLAP.

B.2.4 If a NVLAP-accredited laboratory submits physical standards or test and measurement equipment to a calibration service provider that is not accredited by NVLAP or by an accrediting body with which NVLAP has a mutual recognition arrangement, the laboratory shall:

a) document that an appropriate accredited calibration service provider is not available;

b) audit the claim of traceability of the provider of the calibration service and document the following areas related to the calibration and claim of traceability of its standards and test and measurement equipment:

   1) information regarding assessment of the quality system used by the calibration service provider;

   2) the calibration procedure(s) used by the calibration service provider;

   3) the physical standards or other test and measurement equipment used by the calibration service provider (including evidence of traceability to standards maintained by NIST or an appropriate national metrology institute and copies of relevant calibration certificates);

   4) information regarding the calibration intervals of relevant standards or other test and measurement equipment;

   5) the environmental conditions of the laboratory;

   6) the method(s) by which uncertainties are determined (e.g., Guide to the Expression of Uncertainty in Measurement (GUM); and

   7) the relative uncertainties achieved at all steps of the process;

c) pursue the traceability chain until traceability to appropriate stated references is completely validated, when a calibration service provider submits physical standards and/or test and measurement equipment used in the calibration to another laboratory(s) not accredited by NVLAP;

d) enter the audit documentation, including all findings of nonconformance and resolutions of those findings, into the laboratory's quality management record-keeping system.

NOTE An on-site visit to the provider of the calibration service is encouraged, but is not required as long as the information listed above is obtained and otherwise verified. Self-declaration of compliance to ISO/IEC 17025 or other relevant standards by a calibration service provider is not acceptable evidence of verification of traceability. Citation of a NIST Test Number by the calibration service provider likewise is not acceptable evidence of verification of traceability.

B.2.5 If traceable calibration is not available or appropriate, laboratories may demonstrate comparison to a widely used standard that is clearly specified and mutually agreeable to all parties concerned, particularly in measurements where NIST does not maintain a U.S. national standard. For example, NIST does not maintain a standard for all hardness testing scales. There are several widely used commercial standards available for hardness. However, these standards may not all give equivalent measurement results; therefore, it is important to specify which standard is used and to obtain agreement among all parties involved that the choice made is acceptable.

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